

EU Declaration of Conformity

Manufacturer:	Granberg AS Bjoavegen 1442, NO-5584 Bjoa, Norway	E-mail: post@granberg.no Phone: +47 53 775 300
Single Registration number (SRN):	NO-MF-000000207	

Art. 114.770

Disposable Examination and Protective Gloves by Granberg, nitrile, non-sterile, powder-free, blue colour.

The item is in conformity with (EU) 2017/745 Medical Device Regulation as:

Risk Classification	Class I according to Rule 1 and 5 of Annex VIII of Regulation (EU) 2017/745
Applied normative standards	EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009, ISO 15223-1:2021
Intended Use	Powder-free examination and protective disposable nitrile gloves intended for use in the medical field to protect patients and users from cross-contamination. These gloves are also intended to protect against certain chemicals and microorganisms where hand protection is needed.
Basic UDI-DI	702377GR114NNSQ9

The product described above is also meeting requirements of **Category III** Personal Protective Equipment (PPE) and complies with the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on Personal Protective Equipment and European harmonized Standards EN 420:2003+A1:2009, EN 374-1:2016 as **Type B**, EN 374-5:2016 including **virus** protection.

The product is identical to the PPE, which is the subject of EU Type Examination (Module B) certificate of conformity no. **F118/962502** issued by Notified Body:

SGS Fimko Oy, (NB No. 0598), Takomotie 8, 00380 Helsinki, Finland.

Furthermore, the product is subject to the Conformity to type based on quality assurance of the production process (Module D) of the Regulation 2016/425 under the surveillance of the Notified Body:

SGS Fimko Oy, (NB No. 0598), Takomotie 8, 00380 Helsinki, Finland.

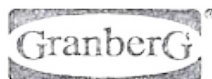
This Declaration of Conformity is issued under the sole responsibility of the manufacturer – Granberg AS.

Signed for Granberg AS:



Ole Marthon Granberg

Managing Director



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